out and distinctly claim the subject invention, in order to assist Examiner Sisson's review of the prior art search, and to expedite the prosecution of the subject application. No agreement was reached, however, Mr. Schodin thanked Examiner Sisson for a productive interview, which served to bring into sharper focus questions regarding the patentability of the claimed subject matter.

Discussion of Claim Amendments

The claims have been amended to more particularly point out and distinctly claim the subject invention.

Claim 1 has been amended to make it more clear that the processing of a sample (*See*, preamble original claim 1) serves to reduce contamination in a nucleic acid analyzer. The specification extensively describes a nucleic acid analyzer, one embodiment of which is depicted in Figure 3. An additional step, step (a) as pending, has also been added to these claims to provide additional structure to these claims, thereby better illuminating the metes and bounds of the claimed subject matter by defining the claimed subject matter more independently of the detailed description of the invention in the specification . This claim amendment is supported in the specification, for example, at page 57, lines 14-17. Claim 1 also has been amended to replace the term "conductor" with the term --electrically conductive surface--. The specification, as well as the originally pending claim, support this claim amendment. Specific support in the specification can be found at, for example, page 57, line 25, and page 55, line 26, to page 56, line 2.

The preamble of claim 2 has been amended to make it clear that the processing of a sample (recited in preamble of originally filed claim) serves to separate a pair of binding members from each other in a sample container of an analyzer. The separation of binding members is described in the specification, for example, in step (d) of the originally filed

claim, and the context of the analyzer is presented throughout the specification, which is easily observed in Figure 3. Support for changing the terms "conductor" to -- electrically conductive surface-- and "conductor" to --electrode-- is discussed with respect to claim 1 (in the preceding paragraph).

Claim 3 has been cancelled without prejudice.

Claim 4 has been amended to make it more clear that the processing of a sample (recited in preamble of originally filed claim) serves to reduce contamination of a reusable PCR reaction vessel. This amendment is supported by the specification, for example, at page 56, lines 27-30. An additional step, step (a) as pending, has also been added to these claims to provide additional structure to these claims, thereby better illuminating the metes and bounds of the claimed subject matter by defining the claimed subject matter more independently of the detailed description of the invention in the specification . This claim amendment is supported in the specification, for example, at page 57, lines 14-17. Claim 4 also has been amended to replace the term "conductor" with the term --electrically conductive surface--. The specification, as well as the originally pending claim, support this claim amendment. Specific support in the specification can be found at, for example, page 57, line 25, and page 55, line 26, to page 56, line 2.

The preamble of claim 5 has been amended to make it clear that the processing of a sample (recited in preamble of originally filed claim) serves to separate a pair of binding members from each other in a sample container of an analyzer. The separation of binding members is described in the specification, for example, in step (d) of the originally filed claim and at page 53, lines 29-31, and the context of the analyzer is presented throughout the specification, which is easily observed in Figure 3. Support for changing the terms "conductor" to -- electrically conductive surface-- and "conductor" to --electrode-- is discussed with respect to claim 1 (in the preceding paragraph).

Claim 6 has been cancelled without prejudice.

New claim 7 depends from claim 1 and recites an electrically conductive pipettor. The specification describes an electrically conductive pipettor at page 57, lines 28-31.

New claim 8 depends from claim 7, and the subject matter defined therein is described in multiple places in the specification, including page 57, line 28, to page 58, line 13.

New claims 9, 10, and 11 recite subject matter described throughout the specification as a whole..

New claim 12 is directed to a method of reducing the ability of a nucleic acid to be amplified or detected in a PCR reaction process including the step of applying a voltage to fragment the nucleic acid. The method of claim 12 is described in the specification, for example, at originally filed claim 1 and at page 58, line 18.

New claim 13 is directed to the method of claim 12 performed in a nucleic acid analyzer. The specification extensively describes a nucleic acid analyzer, one embodiment of which is depicted in Figure 3.

New claims 14-16 are directed to a method of amplifying a nucleic acid wherein a nucleic acid is bound to a particle to substantially separate the nucleic acid from other components in a sample and eluted from the solid support by applying a voltage before amplifying the nucleic acid. This method is described throughout the specification. The application of a voltage to elute the nucleic acid from a solid support is described at page 3, lines 7-13, page 18, line 27, page 53, line 31, page 56, line 18, and page 57, lines 14-17

Discussion of Patentability of the Claimed Subject Matter

A. *Discussion of Cheng et al. (U.S. Patent 6,071,394)*

Cheng et al. is directed to sample separation and preparation for a DNA diagnostic assay system (column 4, lines 32-40) in which cells are lysed by a dielectrophoretic field (column 5, lines 4-14), and the nucleic acids therein are isolated using a dielectrophoretic field for the purposes of enzymatic or hybridization assays (passim, see esp., column 5, lines 46-51). Cheng et al. fails to teach or reasonably suggest the present inventive method. For example, with respect to claims 1 and 4, Cheng et al. fails to disclose the use of electric fields to decrease the ability of the isolated nucleic acids to be amplified in a PCR reaction. With respect to claims 2 and 5, Cheng et al. fails to describe an instrument capable of nucleic acid preparation, amplification, and detection. With respect to claim 12, Cheng et al. fails to disclose fragmentation of nucleic acids. With respect to claim 14, Cheng et al. fails to disclose nucleic acid amplification. All other pending claims depend from these claims, and by definition, therefore, Cheng et al. also fails to teach or reasonably suggest the method of these claims.

*B. Bases of Rejection in the Record*

The only claim rejection of record in the subject application is an enablement rejection. The Office Action states that the specification must enable one skilled in the art to practice the claimed invention, omitting no more than minor details. By inference then, the Office Actions take the position that the amount of electrical current to be passed through the reaction vessel must not be a "minor detail." In the event that this rejection is maintained upon the renewed examination of this application, applicants respectfully traverse.

The specification more than amply guides the ordinarily skilled artisan, particularly at page 53, line 23, to page 56, line 2, how to construct a circuit suitable for delivering an effective amount of current to a reaction vessel, and exemplary electrical conditions for

operating the circuit, thereby enabling the skilled artisan to practice the full scope of the claimed method.

Moreover, even if the Office were to take the position that for some embodiments, some experimentation would be required to practice the claimed invention, this still would not render the claimed methods unpatentable. Rather, a specification is legally enabling unless under the circumstances the level of experimentation required to achieve the claimed result is "undue" (In re Wands, of record). Applicants submit that, irrespective of whether the level of experimentation required, *if any*, is viewed under the Forman factors enunciated in In re Wands (of record) or even from a common sense perspective, that level of experimentation (if any) is trivial, and clearly not undue.

Additionally, a specification is deemed to enable the ordinarily skilled artisan to practice the claimed invention unless the Patent Office adduces sufficient evidence to doubt that this presumption. However, the only evidence of record of any uncertainty in the ability of the ordinarily skilled artisan to practice the claimed invention is derived from U.S. Patent 5,200,313 to Carrico. Carrico, however, does not pertain to any of (i) the reduction of contamination in a reaction vessel, (ii) the separation of binding pairs, or (iii) an other embodiment of the present inventive method. Accordingly, the specification should be legally deemed to fully enable the ordinarily skilled artisan to practice the claimed method.

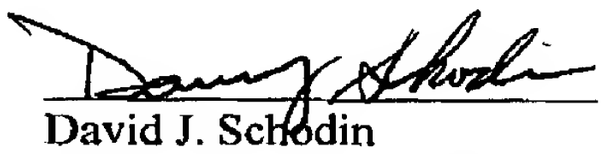
The Office has also expressed concern as to whether practicing the invention defined by claim 1 would prevent the use of the reaction vessel when a subsequent set of reactants were added to the reaction vessel prior to the execution of the claimed invention. In this regard, the Examiner suggested that the timing of the addition of additional reactants or reagents into the reaction vessel might need to be stated in the claims. Applicants respectfully disagree. The performance of subsequent reactions are not within the claimed

subject matter, and accordingly, it is not permissible to read this additional limitations into the claim.

Conclusion

The Examiner is respectfully requested to pass the subject application to allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the present application, the Examiner is invited to telephone applicant's undersigned representative.

Respectfully submitted,
G. Gundling



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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: G. Gundling, et al.

Application No.: 09/492,213

Filed: January 27, 2000

Title: METHOD OF PROCESSING A SAMPLE CONTAINING AT LEAST ONE BIOLOGICAL ELEMENT

Case No.: 6416.US.P1

Group Art No.: 1655

Examiner: B. Sisson

Assistant Commissioner for Patents
Washington, D.C. 20231

**ATTACHMENT TO PRELIMINARY AMENDMENT**

**TRANSMITTED MAY 24, 2001**

Dear Sir:

Pursuant to 37 C.F.R. § 1.121, applicants provide herein marked-up copies of each claim that was pending prior to the entry of, and amended by way of, the Preliminary Amendment transmitted via facsimile on May 24, 2001.

1. (Amended) A method of processing a sample [containing at least one biological element] to reduce contamination in a nucleic acid analyzer, the method comprising the steps of:

(a) providing a nucleic acid analyzer containing a first sample, wherein the first sample comprises a first nucleic acid

that could contaminate a PCR reaction to be performed on a second sample;

(b) [(a)] [introducing] contacting a first [conductor] electrically conductive surface and a second [conductor] electrically conductive surface to [into the] a portion of the first sample [containing at least one biological element];

(c) [(b)] applying a voltage between the first [conductor] electrically conductive surface and the second [conductor] electrically conductive surface; and

(d) [(c)] adjusting the voltage to reduce [an] the ability of the [at least one biological element] first nucleic acid in the waste portion of the first sample to be amplified or detected in a PCR reaction process involving the second sample.

2. (Amended) A method of [processing a sample containing at least one biological element] separating a binding pair consisting of a first binding member from a second binding member when the first binding member is bound to the second binding member and in a sample container of an analyzer capable of nucleic acid preparation, amplification, and detection, the method comprising the steps of:

(a) [removably attaching the at least one biological element in the sample to a binding member] providing the container of the analyzer containing a first binding member bound to a second binding member;

(b) introducing a first [conductor] electrically conductive surface and a second [conductor] electrically conductive surface into the [sample] container;

(c) applying a voltage between the first [conductor] electrically conductive surface and a second [conductor] electrically conductive surface into the [sample] container;

(d) adjusting the voltage such that the [biological element in the sample is removed from the binding member] bond between the first binding member and second binding member is broken.

4. (Amended) A method of [processing a sample containing at least one biological element] reducing contamination in a reaction vessel used for PCR, the method comprising the steps of:

(a) providing a reaction vessel containing a first sample, wherein the first sample contains a nucleic acid that could contaminate a PCR reaction to be performed on a second sample;

(b) [(a)] locating a first [conductor] electrode and a second [conductor] electrode adjacent to the [sample] contaminating nucleic acid;

(c) [(b)] applying a voltage between the first [conductor] electrode and the second [conductor] electrode; and

(d) [(c)] adjusting the voltage to reduce an ability of the [at least one biological element in the sample] contaminating nucleic acid to be amplified or detected in a PCR reaction.

5. (Amended) A method of [processing a sample containing at least one biological element] separating a binding pair consisting of a first binding member from a second binding member when the first binding member is bound to the second binding member and in a sample container of an analyzer capable of nucleic acid preparation, amplification, and detection, the method comprising the steps of:

(a) [removably attaching the at least one biological element in the sample to a binding member] providing the container of the analyzer containing a first binding member bound to a second binding member;

(b) locating a first [conductor] electrode and a second [conductor] electrode adjacent to the [sample] container;

(c) applying a voltage between the first [conductor] electrode and the second [conductor] electrode; and

(d) adjusting the voltage such that the [biological element in the sample is removed from the binding member] bond between the first binding member and second binding member is broken.